

ENTERED

October 07, 2022

Nathan Ochsner, Clerk

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF TEXAS
HOUSTON DIVISION**

TAMMY PIZZITOLA,
Plaintiff,

v.

ETHICON, INC. and
JOHNSON & JOHNSON,
Defendants.

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CIVIL ACTION NO. 4:20-CV-02256

ORDER

Before the Court is the Motion to Exclude Peggy Pence, Ph.D. filed by Defendants Ethicon, Inc. and Johnson & Johnson. (Doc. No. 161). Plaintiff Tammy Pizzitola has filed a response in opposition. (Doc. No. 167). The Court hereby **grants** in part and **denies** in part the motion.

I. Legal Standard

Defendants' motion was filed primarily under the principles set in *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993) and *Kumho Tire Co. v. Carmichael*, 526 U.S. 137 (1999). *Daubert*'s holdings have been summarized as follows:

Reliable testimony must be grounded in the methods and procedures of science and signify something beyond "subjective belief or unsupported speculation." *Daubert*, 509 U.S. at 590, 113 S.Ct. 2786. The inferences or assertions drawn by the expert must be derived by the scientific method. *Id.* In essence, the court must determine whether the expert's work product amounts to "good science." *Daubert v. Merrell Dow Pharms., Inc.*, 43 F.3d 1311, 1315 (9th Cir. 1995) ("Daubert II") (quoting *Daubert*, 509 U.S. at 593, 113 S.Ct. 2786). In *Daubert*, the Supreme Court outlined factors relevant to the reliability prong, including: (1) whether the theory can be and has been tested; (2) whether it has been subjected to peer review; (3) the known or potential rate of error; and (4) whether the theory or methodology employed is generally accepted in the relevant scientific community. *Daubert*, 509 U.S. at 593–94, 113 S.Ct. 2786. The Supreme Court emphasized the "flexible" nature of this inquiry. *Id.* at 594, 113 S.Ct. 2786. As later confirmed in *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 119 S.Ct. 1167, 143 L.Ed.2d 238 (1999): "*Daubert*'s list of specific factors neither

necessarily nor exclusively applies to all experts or in every case. Rather the law grants a district court the same broad latitude when it decides how to determine reliability as [the court] enjoys in respect to its ultimate reliability determination.” *Id.* at 141–42, 119 S.Ct. 1167.

Abarca v. Franklin Cty. Water Dist., 761 F. Supp. 2d 1007, 1021 (E.D. Cal. 2011).

While *Daubert* attacks usually focus on a witness’ reliability, some courts have also included an attack on a witness’ qualification (or lack thereof) under the *Daubert* umbrella. Defendants’ motion has the elements of both.

II. Prior *Daubert* Rulings of the MDL Court

At the onset, the Court notes that Defendants assert in their motion that both sides have agreed to be bound by the *Daubert* rulings previously made by the MDL Court. (Doc. No. 161 at 2, citing Doc. No. 159). While the parties stipulated to be bound by those rulings for purposes of the trial in this case, each side apparently reserved the right to appeal those rulings at the appropriate time post-judgment. This, of course, puts this Court in a somewhat interesting position. It can reject or accept such stipulation and then later be second-guesses on appeal for a ruling it did not make or reject the stipulation that both sides have endorsed. While this Court finds it highly unlikely that one can agree to be bound by a ruling and then appeal that very same ruling, it accepts the parties’ stipulation.

That being the case, there are various objections contained in Defendants’ motion that this Court need not address as they were already addressed in the MDL and were repeated by the Defendants here only as a means of preserving the Defendants’ objection to the ruling.

III. Defendants’ Motion

Dr. Peggy Pence is a toxicologist, not a medical doctor. Nevertheless, she has spent a good portion of her career working in the research and development of medical devices,

including work in the subfield of clinical testing. Thus, she is familiar with many of the pertinent areas to this lawsuit.

Defendants seeks to limit Dr. Pence's testimony in such a fashion that she should not be allowed to testify about:

1. The Prolift +M;
2. Ethicon's alleged failure to conduct appropriate testing of the TVT-O;
3. The misbranding of the TVT-O due to failure to warn and false or misleading labeling;
4. The inadequacy of TVT-O labeling and how the labeling did not support adequate consenting of patients; and
5. The misbranding of the TVT-O due to failure to meet the post-market vigilance standard of care.

This last complaint listed above has already been addressed and excluded by the MDL Court. Consequently, this Court need not address it. With respect to Dr. Pence's opinions regarding the alleged failure to conduct appropriate pre-market testing of the TVT-O, the MDL Court has already overruled the portion of the objection aimed at Dr. Pence's qualifications, so this Court need only address the objection to the reliability of her opinion. Similarly, with respect to her purported testimony concerning the failure to warn and the false and misleading labeling, the MDL Court denied the Defendants' objections to the reliability of her opinions but did not rule upon whether she applied the wrong legal standard. The MDL Court also found that Dr. Pence had the qualifications to testify concerning alleged misbranding both in terms of the failure to warn (and whether the labeling was false and misleading) and in terms of whether it provided enough information to allow a doctor to obtain informed consent. The MDL Court specifically reserved for the trial courts to decide whether Dr. Pence could opine on the issue of informed consent itself.

IV. Prolift +M Testimony

The first issue is the simplest. Dr. Pence is hereby precluded from testifying in any fashion about the Prolift +M product. Her report does not address this product. This issue is less of a *Daubert* issue and more of one that falls under the auspices of the Rules of Civil Procedure. Rule 26(a) states that an expert's report must contain "(i) *a complete statement of all opinions* the witness will express and the basis and reasons for them; (ii) the facts or data considered by the witness in forming them," and "(iii) any exhibits that will be used to summarize or support them. . . ." Fed. R. Civ. P. 26(a)(2)(B) (emphasis added). A party's failure to provide timely expert disclosures under Rule 26 precludes the party from "us[ing] the information or witness to supply evidence on a motion, at a hearing, or at a trial, unless the failure was substantially justified or is harmless." *Davis v. Davis*, No. 2:12-CV-166, 2017 WL 896299, at *4 (S.D. Tex. Mar. 7, 2017) (quoting Fed. R. Civ. P. 37(c)(1)).

Plaintiff in response to the Defendants' motion does not even attempt to take on the topic of Prolift +M. Consequently, even if Dr. Pence did opine in this area, Plaintiff has waived the right to present that testimony.

V. TVT-O Testimony

The Court finds that the specific objections raised as to Dr. Pence's TVT-O testimony (including her failure to apply the Global Harmonization Task Force ("GHTF") guidelines,¹ her failure to survey the medical literature for clinical data, the fact that she did not apply the standards she cites, and her alleged failure to consider pre-existing medical literature and FDA medical panel findings) may certainly undermine her testimony in the eyes of a jury if raised

¹ This Court reserves ruling on the admissibility of any testimony concerning the GHTF guidelines because, as the MDL Court found with respect to the FDA section 510(k) testimony, it finds serious questions concerning their admissibility.

during a rigorous cross-examination, but they do render her opinions with regard to testimony to be inadmissible.

This is the type of “[s]haky but admissible evidence” that must “be attacked by cross examination, contrary evidence and attention to the burden of proof, not exclusion.”

Icon-IP Pty Ltd. v. Specialized Bicycle Components, Inc., 87 F. Supp. 3d 928, 941 (N.D. Cal. 2015) (quoting *Primiano v. Cook*, 598 F.3d 558, 564 (9th Cir. 2010)). The objections to Dr. Pence’s testimony are overruled.

With regard to her proposed “misbranding” testimony, Defendants’ primary complaint is that Dr. Pence simply ignores the knowledge level of physicians that use the TVT-O. The Defendants correctly point out that a device manufacturer is generally under the burden to adequately warn the end user, which in this case, is the learned intermediary. The Plaintiff, in her response, concedes that the duty is to provide adequate warnings to the prescribing physician. This point of contention ultimately encompasses Defendants’ objection concerning Dr. Pence’s ability to discuss informed consent. With regard to this argument, Plaintiff contends that Dr. Pence has relied upon the testimony of other physicians who are actually trained in the surgical treatment of stress urinary incontinence and have implanted the TVT-O product in patients.

This Court cannot prejudge all of the issues involved in this objection because Dr. Pence is clearly qualified to answer some prospective questions and not qualified to respond to others. Therefore, the Court shall set out some general parameters. Dr. Pence may not testify about what constitutes informed consent in Texas. To the extent this topic encompasses a legal matter, this Court will instruct the jury on the applicable law. To the extent this encompasses a medical matter, this will need to be addressed by medical specialists. Dr. Pence is neither an expert in the law, nor is she a physician who practices in this area of medicine or who is familiar with the

standards of practice in this geographic area. As such, she is not qualified in either arena. Secondly, she may not parrot what has been told to her or otherwise made known to her by actual implanting physicians in the area of informed consent. It has long been held that, while an expert may rely on hearsay, an expert's testimony cannot be used as a vehicle for parading hearsay in front of a jury.


All this is not to say she may not address the warnings issue in terms of the adequacy of Instructions for Use ("IFU") based upon her training and experience, as long as she (to use a popular phrase) stays in her lane, which the Court finds to be the regulatory side and not the practicing medicine side.

VI. Conclusion

Defendants' Motion to Exclude Peggy Pence, Ph.D. is **granted** in part and **denied** in part. The stipulation concerning the prior rulings of the MDL Court is adopted. The motion to exclude any testimony by Dr. Pence concerning Prolift +M is **granted**. The motion to exclude all legal opinions and conclusions as to the governing standards and testimony concerning appropriate informed consent is **granted**.

The motion to exclude as it pertains to Dr. Pence's testimony concerning appropriate testing is **denied**. The motion to exclude Dr. Pence's testimony concerning the TVT-O IFU is hereby deferred to trial as it hinges on the actual questions put to her.

SIGNED at Houston, Texas this 7th day of October, 2022.



Andrew S. Hanen
United States District Judge